

Claims 15-49 depend from claim 14 and are narrower in scope than claim 14. Accordingly, the applicants would be understood by one of skill in the art to possess the inventions recited by these narrower claims as well.

New claims 49-59 each recite a small genus for which the applicants have described a representative number of species:

Claim 49 focuses on the aspect of the invention in which the structural and early polypeptides are *human* papillomavirus polypeptides.

Claim 50 focuses on the aspect of the invention in which the human papillomavirus is *HPV 16, HPV 18, HPV 33, HPV 35 or HPV 45*.

Claim 51 focuses on the aspect of the invention in which the structural human papillomavirus polypeptide is encoded by *L1-ORF* (or a fragment thereof) and the early human papillomavirus polypeptide is encoded by *E6-ORF or E7-ORF* (or a fragment thereof).

Claim 52 focuses on the aspect of the invention in which the structural human papillomavirus polypeptide is encoded by *HPV 16 or 18 L1-ORF (or a fragment thereof)* and the early human papillomavirus polypeptide is encoded by an *HPV 16 or 18 E6-ORF or E7-ORF (or a fragment thereof)*.

Claim 53 focuses on the aspect of the invention in which the structural human papillomavirus polypeptide is encoded by *HPV 16 or 18 L1-ORF* and the early human papillomavirus polypeptide is encoded by *HPV 16 or 18 E6-ORF and E7-ORF*. Claim 54 focuses on the aspect of the invention in which the structural human papillomavirus polypeptide and the early human papillomavirus polypeptide are encoded by *HPV 16 ORFs*, and claim 55 focuses on the aspect of the invention in which these polypeptides are encoded by *HPV 18 ORFs*.

Moreover, new claims 56 to 59 depend from claim 53 and recite the following:

- claim 56 requires HPV 16, E1 and E6 ORFs;
- claim 57 requires HPV 18, E1 and E6 ORFs;
- claim 58 requires HPV 16, E1 and E7 ORFs; and
- claim 59 requires HPV18, E1 and E7 ORFs.

## 2. The pending claims satisfy the enablement requirement of 35 U.S.C. § 112.

To be enabling, the specification must simply set forth "a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same."<sup>1</sup>

The Examiner has conceded the enablement of the invention for specifically exemplified aspects of the invention:

an AAV vector comprising a nucleic acid coding for a fusion polypeptide comprising a structural papilloma virus polypeptide and a non-transforming polypeptide, wherein the fusion polypeptides comprise a polypeptide coded by HPV-16 L1-ORF and a polypeptide coded by HPV 16 E6-ORF and E7-ORF, and another fusion polypeptide coded by HPV 18 L1-ORF and a polypeptide coded by HPV 16 E6-ORF and E7-ORF.<sup>2</sup>

New claims 52 to 59, as described more fully above, are directed to these combinations, conceded by the Examiner to be enabled.

However, the applicants' disclosure clearly entitles the applicants to broader claims than those recited in claims 52 to 59. The applicants' disclosure enables one skilled in the art to obtain, without undue experimentation, more than what is recited in these narrow claims. It is not necessary for the patent document to read like a production specification—a requirement for some experimentation does not prevent the satisfaction of the enablement requirement.<sup>3</sup> In view of the applicants' disclosure and without undue experimentation, one skilled in the art can readily obtain fusion polypeptides, as recited in claim 14, wherein (1) the structural papillomavirus polypeptide is encoded by L1-ORF or L2-ORF (or fragments), and (2) the early papillomavirus polypeptide of claim 14 is encoded by E1-ORF, E2-ORF, E4-ORF, E5-ORF, E6-ORF, E7-ORF (or fragments). In other words, the applicants have enabled this small genus of fusion polypeptides. The remaining claims all require, at a minimum, these same limitations.

Accordingly all claims are enabled, and the applicant therefore respectfully requests the Examiner to withdraw the enablement rejections.

1. \_\_\_\_\_

<sup>1</sup> 35 U.S.C. § 112.

<sup>2</sup> Office Action of February 2, 2000, paragraph bridging pages 4 and 5.

<sup>3</sup> Northern Telecom, Inc. v. Datapoint Corp., 15 U.S.P.Q.2d 1321, 1329 (Fed. Cir. 1990).

### 3. The pending claims are nonobvious in view of Bournnell et al. and Bartlett et al.

Claim 14 (which corresponds to original claim 1) requires the following components:

- (1) a structural papillomavirus polypeptide encoded by L1-ORF or L2-ORF (or fragments); and
- (2) an early papillomavirus polypeptide encoded by E1-ORF, E2-ORF, E4-ORF, E5-ORF, E6-ORF, or E7-ORF (or fragments).

The Examiner contends that Bournnell et al. teaches a fusion protein encoded by part or all of E6 and E7. However, while such a fusion polypeptide would satisfy the requirements of (2), there is no teaching or suggestion of a fusion polypeptide with the components of (1). Bartlett et al. is simply a review article describing the state of the art with respect to adeno-associated viruses, and therefore does not remedy the lack of teaching of Bournnell with respect to the requirement of a structural papillomavirus polypeptide encoded by L1-ORF or L2-ORF (or fragments).

While the applicants claimed invention does not exclude a fusion protein having components encoded by E6 and E7, the claims to the applicants' invention also *require* a structural papillomavirus polypeptide encoded by L1-ORF or L2-ORF (or fragments). This requirement is not taught or suggested by the cited references; therefore, the cited references do not render the claimed invention obvious.

The Examiner is respectfully requested to withdraw the 35 U.S.C. § 103 rejections.

### 4. Fees Payable

The entry of this amendment results in a total of 53 claims pending in the application, including 33 total claims (\$297) and 4 independent claims (\$156) beyond the number for which a fee has been paid. Accordingly, an added claims fee of \$453 is due. A check for this amount is submitted herewith. Please charge any deficiency in payment, and credit any excess, to Deposit Account No. 08-3284 of Intellectual Property/Technology Law.

**Petition Under 37 CFR § 1.136 For One Month Extension of Time**

Petition is hereby made for a one-month extension of the term for response to the February 3, 2000 Office Action, extending the deadline for response to June 3, 2000.

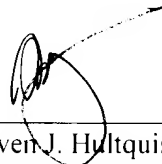
The petition fee of \$55.00 for this petition is enclosed, together with the above-identified added claims fee of \$292.00, for a total fee payable of \$347.00, by the enclosed check payable to Commissioner of Patents and Trademarks in such amount. Please charge any deficiency or credit any excess payment to deposit account number 08-3284 of Intellectual Property/Technology Law.

**CONCLUSION**

On the basis of the amendments and arguments presented above, the applicants have established that the claims now pending in the application satisfy the requirements of 35 U.S.C. §§ 102, 103 and 112. All pending claims are in form and condition for allowance.

If any issues remain outstanding, the Examiner is requested to contact the undersigned attorney at (919) 419-9350 so that all issues may be resolved and the application may issue at the earliest possible date.

Respectfully Submitted,



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